

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE**

**IN RE: VALSARTAN, LOSARTAN,
AND IRBESARTAN PRODUCTS
LIABILITY LITIGATION**

MDL No. 2875

Honorable Robert B. Kugler,
District Court Judge

This Document Relates to All Actions

SPECIAL MASTER ORDER NO. 84

I. BACKGROUND

On December 14, 2022, more than eighteen months after the June 1, 2021 deadline for the completion of the “first phase of fact discovery,” (Case Management Order No. 23 (ECF No. 863) at 1), Defendants Zhejiang Huahai Pharmaceutical Co., Ltd., Huahai U.S., Inc., Princeton Pharmaceutical Inc., and Solco Healthcare US, LLC (collectively, “the ZHP Defendants”), issued a subpoena for the production of documents to non-party Valisure LLC.¹ (*See* ECF No. 2217-4.) The subpoena sought production of “[d]ocuments sufficient to

¹ Valisure identifies itself as “an online pharmacy . . . and an analytical laboratory that is ISO 17025 accredited by the International Organization for Standardization (‘ISO’).” (Valisure “Citizen Petition” to the FDA dated June 13, 2019 (ECF No. 1984-1 at 2.))

identify the NDC² of all Novartis Product referenced in the Citizen Petition submitted by Valisure” (*Id.* at 8.) The Valisure Citizen Petition, sent in June of 2019, reported test results for valsartan-containing drugs (“VCDs”), including VCDs sold by Novartis that showed detectable levels of nitrosamines, a suspected carcinogen. The specific VCDs tested by Valisure, however, are not disclosed in the Citizen Petition and accompanying test results.

The ZHP Defendants have moved to compel production of that information. (ECF No. 2217.) Plaintiffs oppose that motion and have cross-moved for a protective order, asking that the Valisure subpoena be quashed. (ECF No. 2227.)

It is undisputed that a generic drug, like the VCDs produced by the ZHP Defendants, must have those same active ingredients as does the “Reference Listed Drug” (“RLD”). The ZHP Defendants seek the NDCs for the samples tested by Valisure to determine whether Valisure tested the Novartis brand-name products, Diovan and Exforge, the “Reference Listed Drug” for the generic Valsartan. Plaintiffs’ experts have stated that Diovan and Exforge do not contain any detectable amounts of NDMA, and the fact that the ZHP Defendants’ generic

² NDC is the acronym for the National Drug Code, which identifies drugs sold in the United States by “a unique, three-segment number . . . which serves as the FDA’s identifier for drugs. FDA publishes the listed NDC numbers in the NDC Directory which is updated daily.” National Drug Code Directory, <https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory> (Last visited Aug. 28, 2023.)

VCDs contain NDMA means that they have violated the duty of “sameness,” *i.e.*, the requirement to have the same active ingredients in the generic drug as found in the RLD. The presence of detectable amounts of NDMA in Diovan or Exforge could undermine the opinions of Plaintiffs’ experts.

Plaintiffs have moved to quash the Valisure subpoena, arguing that it seeks discovery long after the deadline for completion of fact discovery for information that has little to no relevance here. Contrary to Plaintiffs’ assertions, however, it does appear that the subpoena seeks discovery of potentially relevant information. Indeed, discovery had been ordered with respect to the purported validation of the Valisure testing by one of Plaintiffs’ experts, Dr. Najafi. (*See* Special Master Order No. 68, ECF No. 2137.) That Order, however, was issued in July of 2022, granting a motion that had been filed in April of 2022. (ECF No. 2013.)

The ZHP Defendants have not offered any compelling justification for waiting until December of 2022, more than one year after the close of fact discovery, to seek information from Valisure concerning its testing. The ZHP Defendants assert that “it was not clear . . . that the identity of the Novartis products referenced [in the Valisure Citizen Petition] would be a contested issue in this case until: (1) plaintiffs’ expert Dr. Ron Najafi disclosed his role in validating the testing results underlying the Citizen Petition during his 2022 deposition . . . ; (2) plaintiffs’ counsel suggested in subsequent briefing that the Novartis product

tested by Valisure was not Diovan or Exforge, but a generic valsartan product . . . ; and (3) a number of plaintiffs’ experts disclosed opinions on October 31, 2022 based on the assumption that neither Diovan nor Exforge contains any nitrosamines.” (ECF No. 2248 at 2-3.)

The ZHP Defendants’ complaint that it only recently appreciated the significance of the Valisure testing rings hollow. They knew as early as November of 2021, more than one year before the ZHP Defendants issued the Valisure subpoena, that Dr. Najafi’s opinions were based upon the assumption that neither Exforge nor Diovan contained nitrosamine. (*See* Nov. 4, 2021 Report of Ron Najafi, Ph.D., ECF No. 1748-3.)

Discovery deadlines are important. They enable the record to be set for such significant events as class certification and summary judgment motions. In this case, the ZHP Defendants are seeking to pursue discovery after Plaintiffs presented their expert witness reports on liability and well after briefing and decisions on class certification issues. The ZHP Defendants were aware of the Valisure Citizen Petition for many months before seeking identification of the NDC numbers for the substances disclosed in that petition. Plaintiffs have signaled that production of the NDC numbers could prompt the need for additional discovery concerning the reliability and adequacy of Valisure testing, observing that some the same Defendants present in this case “have argued in other cases that Valisure’s work is

too unreliable even to form an ‘information or belief’ to plead contamination in a complaint at the Rule 12(b)(6) stage. . . .” (ECF No. 2227 at 14.) Thus, enforcing the Valisure subpoena raises the specter of even more discovery.

Furthermore, if the ZHP Defendants were of the opinion that Exforge or Diovan contain nitrosamines, they were free to conduct their own testing to confirm those beliefs. That they did not do so is no reason to open discovery that should have concluded long ago.

ACCORDINGLY, IT IS HEREBY ORDERED THAT:

1. The ZHP Defendants’ Motion to Compel Compliance with the subpoena issued to Valisure LLC (ECF No. 2217) is **DENIED**.
2. Plaintiffs’ cross-motion for a Protective Order (ECF No. 2227) is **GRANTED** and Defendant ZHP’s Subpoena Duces Tecum to Valisure is hereby **QUASHED**.

s/ Thomas I. Vanaskie
Hon. Thomas I. Vanaskie (Ret.)
Special Master